

MAC setting forth the reasons for disagreeing with the decision of the ALJ.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period.

(ii) The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the MAC finds good cause under the standard established in §§ 405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the MAC considers the enrollee's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the MAC about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the MAC

will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction over the case within 60 calendar days after the date of the ALJ's written decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

Subpart V—Part D Marketing Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise note.

§ 423.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(5) May include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks

and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010]

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.*

(1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when appli-

cable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Ad hoc enrollee communication materials.* Ad hoc enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19826, Apr. 15, 2010]

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or